K124021

5 510(k) Summary

JUN 30 2014

Submitter:	ARKRAY Factory, Inc. 1480 Koji, Konan-cho Koka-shi, Shiga, JAPAN, 520-3306
Contact Person:	Lonna M. DenDooven Regulatory Affairs Specialist ARKRAY Factory USA, Inc. 5182 West 76th Street Edina, Minnesota, USA 55439 Phone: (952) 646-3175 Fax: (952) 646-3230
Date Prepared:	June 30, 2013
Trade Name:	GLUCOCARD 01 Blood Glucose Monitoring System ReliOn Confirm Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345; Class II
Product Codes:	CGA, NBW
Predicate Device:	GLUCOCARD 01 Blood Glucose Monitoring System (K073416)
Device Description:	The GLUCOCARD 01 Blood Glucose Monitoring System and ReliOn Confirm Blood Glucose Monitoring System consist of a meter, test strips, and control solution for use as an aid to monitor the effectiveness of diabetes control.
Intended Use:	The GLUCOCARD 01 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended for single patient use and should not be shared with other individuals. The ReliOn Confirm Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended for single patient use and should not be shared with other individuals.

Substantial Equivalence Basis:	The new GLUCOCARD 01 Blood Glucose Monitoring System is identical to the GLUCOCARD 01 (k073416, cleared by FDA June 13, 2008) except that the manufacturing process for the GLUCOCARD 01 SENSOR Blood Glucose Test Strip has been modified to allow for more efficient production. The fundamental scientific technology of the modified test strip has not changed. The modifications to the test strip did not require any changes to meter hardware, software or other components of the test system.
Functional and Safety Testing:	A clinical study was conducted with persons with diabetes to evaluate system accuracy and to assess ease of use. Analytical verification testing was performed to evaluate precision, dynamic range/linearity, interfering substances, sample volume, stability and the effect of altitude, hematocrit, and environmental conditions.
Conclusion:	Labeling, bench testing results and clinical testing results support the Indications for Use and the claim of substantial equivalence to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ARKRAY FACTORY INC.
LONNA DENDOOVEN
REGULATORY AFFAIRS SPECIALIST
5198 WEST 76TH ST
EDINA MN 55439

June 30, 2014

Re: K124021
Trade/Device Name: ARKRAY GLUCOCARD™ 01 Blood Glucose Monitoring System
ReliOn Confirm Blood Glucose Monitoring
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW,CGA
Dated: June 18, 2014
Received: June 19, 2014

Dear Ms. Lonna Dendooven:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k124021

Device Name
GLUCOCARD 01 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GLUCOCARD 01 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended for single patient use and should not be shared with other individuals.

The GLUCOCARD 01 SENSOR Plus Blood Glucose Test Strips are intended to be used with the GLUCOCARD 01 Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k124021

Device Name
ReliOn Confirm Blood Glucose Monitoring System

Indications for Use *(Describe)*
The ReliOn Confirm Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended for single patient use and should not be shared with other individuals.

The ReliOn Confirm Plus Blood Glucose Test Strips are intended to be used with the ReliOn Confirm Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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